

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C.20555
Region I
2100 Renaissance Blvd.
King of Prussia, PA 19406-2713

Re: Reply to a Notice of Violation

August 23, 2021

To Whom it May Concern,

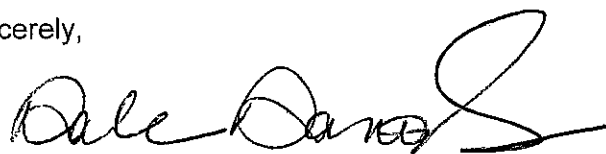
This letter is in response to the letter from the agency dated August 19, 2021 with Document Number 030-01245, License number 06-00843-03, regarding the inspection conducted on April 13-14, 2021 at the Bridgeport, Connecticut facility. Please find our responses to each violation below.

During our inspection, it was determined that the licensee did not conduct its program in accordance with the procedures contained in the letter dated February 20, 2014. Specifically, the licensee calculated the intended dose to be delivered to a lobe or segment of the liver, however, the written directive documented "liver" only instead of specifying the lobe or segment to be treated. The licensee immediately revised the written directive form to capture the intended treatment site (e.g., lobe or segment). In addition, the licensee used a dose calculation method other than the manufacturer's called DAVYR and did not evaluate the method against the manufacturer's method or amend their NRC license to acknowledge the evaluation and use.

- The reason for the violation was that there was an inconsistent approach to the dose calculation methodology used.
- The corrective steps that have been taken and the results achieved as now all physicians will be using the SIRTEX manufacture method henceforth.
- The corrective steps that will be taken to avoid further violations were that this will be an item reiterated in the RSC meeting and all notifications and respective trainings will be provided to each physician henceforth.
- The date when full compliance will be achieved is 8/30/2021

Thank you for reviewing our response. We are happy to respond to any further requests.

Sincerely,

A handwritten signature in black ink, appearing to read "Dale Danowski". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Dale Danowski SVP CNO & COO
St. Vincent's Medical Center
2800 Main St.
Bridgeport, CT 06606
